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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/054,171 | 01/17/2002 | Kai-Uwe Lewandrowski | CSI 126 | 4535 |
| 23579 | 7590 | 07/01/2004 | EXAMINER | |
| PATREA L. PABST PABST PATENT GROUP LLP 400 COLONY SQUARE SUITE 1200 ATLANTA, GA 30361 | | | YU, GINA C | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1617 | |
| DATE MAILED: 07/01/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|-----------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/054,171 | LEWANDROWSKI, KAI-UWE | |
| | Examiner | Art Unit | |
| | Gina C. Yu | 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2003.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-19 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>Aug. 13, 2002</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of Amendment filed on November 26, 2003. Claims 1-19 are pending. Claim rejection made under 35 U.S.C. § 112, first paragraph, as indicated in the previous Office action dated August 26, 2003 is maintained for the reasons of record. Claim rejections made under 35 U.S.C. § 103 (a) are withdrawn in part, and maintained in part, in view of the claim amendments made by applicants. New rejection is made.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detection of osteoporosis caused by bacterial infection, does not reasonably provide enablement for detecting osteoporosis by measuring concentration of other types of pathogens such as viruses, viral produced factors, protozoa, protozoal produced factors, parasites, parasitic produced factors, fungi, and fungal produced factors, as recited in instant claims 12, and 13. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

The enablement test requires require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. See MPEP § 2164.01, reciting In re Wands, 858 F.2d at 737, 8

USPQ2d at 1404 (Fed. Cir. 1988). To determine whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue”, following factors are considered: the breadth of the claims; the nature of the invention; the state of the prior art; the level of one of ordinary skill; the level of predictability in the art; the amount of direction provided by the inventor; the existence of working examples; and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. See In re Wands, at 737

In this case, the scope of the claims is broader than the disclosure in the specification. The efficacy of the invention is unpredictable because of the wide variety of pathogens known to a skilled artisan. No direction or guidance, or working example is given by the inventors with respect to the recited pathogens in claims 12 and 13.

Applicants assert that “assays for infectious agents, factors produced by infectious agents and heat shock proteins are also routine.” Applicants’ argument is not persuasive because the issue here is not whether general method of assays for infectious agents or factors produced by thereof is enabling; the issue is whether the applicants’ disclosure enables the claimed method of screening osteoporosis by running assays for the genus of the infectious agents, factors produced by thereof, and heat shock proteins as recited. For example, the Nair reference teaches that not all bacterial molecular chaperones stimulate bone resorption. Thus one skilled in the art would find it unpredictable to make/use the claimed invention as disclosed. Undue experimentation is required to test the efficacy of the claimed invention and the

disclosure is not enabling the skilled artisan with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-6, 8, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Findlay (WO00/13024) in view of Nair (Calcif. Tissue Int., vol. 64, no. 3, Mar. 1999).

Findlay teaches the method of diagnosing osteoporosis or osteoarthritis by detecting biochemical markers. See p. 3, line 22 – p. 4. The invention includes method steps of taking bone sample and measure or estimate the level of the marker of bone remodeling in the sample by extracting mRNA from the sample, estimating the level of expression for the makers by measuring the quantity of mRNA specific for that marker, and comparing the level to a standard. While the reference teaches using markers associated with bone resorption, the reference fails to teach using the pathogens or heat shock proteins as required by the instant invention. See p. 4, line 16 – p. 5, line 25.

Nair teaches that molecular chaperones (heat shock proteins) stimulate bone resorption. See abstract. The reference teaches that HSP 70 is capable of inducing osteolysis. See p. 217, second column, last par. P. 218, first column, last par. While applicants assert that the claimed invention is directed to HSP's that are "induced in

response to an infectious agents", examiner notes Nair also teaches that "the molecular chaperones released by bacteria may play a role in the pathology of bone infections". See p. 218, first full par. The reference goes on to state, "the finding that mammalian molecular chaperones can also induce calvarial breakdown raises the possibility that release of these conditions not involving bacterial infection."

Given the general teaching in Findley that the method of detection of osteoporosis by screening the concentration of markers associated with bone resorption, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have looked to the prior arts such as Nair for specific types of markers that also stimulate bone resorption.

2. Claims 1, 12-14, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Findley in view of Reddi et al. (J. Bone and Mineral Res., v. 13, no. 8, Aug. 1998) ("Reddi").

Findley, discussed above, fails to teach the specific markers used in the instant invention.

Reddi teaches that the E. coli chaperonin 60 (groEL) stimulates bone resorption and osteoclast formation. See abstract. The reference suggests that bacterial cpn60s may play a role in the osteolysis associated with bone infections. The reference teaches that *Antinobacillus actinomycetemcomitans* causes periodontal bone loss and contains a potent bone-resorbing protein which is also found in cpn60 of E. coli. See p. 1260, col. 2, bridging paragraph. The reference suggests the possibility that bacterial infection

of the chaperonins could be responsible for bone infection diseases such as osteoporosis. See p.1265, col. 1, bridging paragraph.

Given the general teaching in Findley that the method of detection of osteoporosis by screening the concentration of markers associated with bone resorption, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have looked to the prior arts such as Reddie for specific types of markers that also stimulate bone resorption.

Response to Arguments

Applicant's arguments filed November 26, 2003 have been fully considered but they are not persuasive.

Applicants assert that the present invention is the measurement of "HSPs which are induced by infection" rather than bacterial HSPs. Examiner views that there is no patentable distinction in these HSPs because the measured infectious agent or HSPs are induced by bacteria, as evidenced by Nair. See p. 218, first full par.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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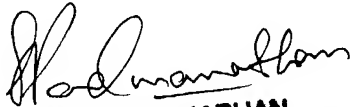
TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-0635. The examiner can normally be reached on Monday through Friday, from 8:30 AM until 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina Yu
Patent Examiner


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER